

REMARKS

Claims 1-7 and 77-79 are pending in the application. Claims 8-76 have been cancelled as drawn to a non-elected invention. Claims 2, 77, and 79 have also been cancelled. Claims 1, 5 and 78 have been amended herein. The amendment to claim 1 is supported by disclosure at page 67, lines 10-11 and page 8, lines 18-22 of the specification. Claims 80-86 have been added. Support for these newly added claims can be found in the specification at pages 65-67. Thus, no new matter has been added. The specification has been amended at page 88, lines 4-10 to correct typographical errors.

Claim rejections

35 U.S.C. §112, first paragraph

Claims 1-7 and 77-79 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner's position is that the specification does not provide enablement for "methods for determining whether a subject has or is predisposed to developing restenosis wherein said methods detect any other alleles in the IL-1 gene cluster [other than IL1RN (VNTR)], including IL-1A(+4845), IL-1B(-511) or IL-1B(+3954)". (Office Action at page 3, bracketed phrase added by Applicants for clarity). Specifically, the Examiner asserts that in view of the unpredictability in the art, undue experimentation would be required to correlate the presence of the above-identified IL-1 polymorphisms with restenosis.

The Examiner has acknowledged, however, that the specification is "enabling for methods for determining whether a SVD patient has or is predisposed to developing arterial restenosis wherein the methods comprise detecting the presence of IL-1RN (VNTR) allele 1 as indicative of a predisposition to arterial restenosis in SVD patients". (Office Action at page 2). The Examiner states further that "the specification has identified...one allele, IL-1RN (VNTR) allele 1, which may be useful for diagnosing susceptibility to restenosis in SVD patients." (Office Action at page 6).

In order to expedite prosecution, and without acceding to the propriety of the Examiner's position, Applicants have amended claim 1 to recite that the IL-1 allele be IL-1RN(VNTR) allele

1 and that the subject be a single vessel coronary artery disease (SVD) subject. As acknowledged by the Examiner, detecting the presence of IL-1RN (VNTR) allele 1 is indicative of a predisposition to arterial restenosis in SVD patients. Accordingly, Applicants submit that amended claim 1 and all claims depending therefrom are fully enabled by the specification as filed. Applicants therefore respectfully request that the enablement rejection be withdrawn.

Claims 80-86 have been added and are directed to a method for determining whether a single vessel coronary artery disease (SVD) subject has or is predisposed to developing restenosis, comprising detecting IL-1RN(VNTR) allele 2 in a nucleic acid sample from the subject, wherein detection of IL-1RN(VNTR) allele 2 indicates that the subject is not predisposed to the development of restenosis. On page 2 of the Office Action the Examiner states that the "specification (pages 66-67) teaches that the IL-1RN (VNTR) allele 2 is associated with a lower restenosis rate in patients with SVD." Accordingly, Applicants submit that claims 80-86 also satisfy the enablement requirement.

On page 4 of the Office Action, the Examiner requests that Applicants provide an explanation as to the apparently conflicting teachings on pages 66-67 of the spec (allele 1 of VNTR markers correlate with predisposition to restenosis) and page 88 of the spec (allele 2 of the 4845, -511, +3954, and VNTR markers correlate with predisposition to restenosis). The explanation is that the recitation of allele 2 on page 88 of the specification was a typographical error. It is evident that such a recitation of allele 2 was a typographical error, as the correlation between allele 1 and predisposition to restenosis was recited multiple times throughout the specification, whereas the recitation of allele 2 and predisposition to restenosis was recited only on page 88. This error has been corrected herein by amendment.

Double Patenting

Claims 1, 3, 4, 6, and 7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of United States Patent Number 6,268,142.

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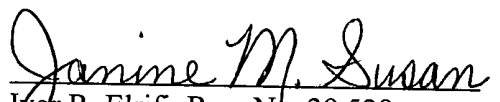
Similarly, claims 1-7 and 77-79 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of United States Patent Number 6,210,877.

Once allowable claims are obtained, a terminal disclaimer will be filed. Until such allowable claims are obtained, Applicants respectfully request that such rejections be held in abeyance.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance, and a Notice of Allowance is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,


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